REMARKS

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein remarks, which place the application in condition for allowance.

Attached hereto is a marked up version of the changes made to the specification by this amendment. The attachment is captioned "**Version With Markings to Show Changes Made.**"

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 3-6, 8-19 and 23-39 are pending. Claims 1 and 5 have been amended; claims 2, 7 and 20-22 have been cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents; and, claims 24-39 have been added to better define and more distinctly claim the instant invention. Support for the amended and added claims is found throughout the specification.

No new matter is added.

It is submitted that these claims are patentably distinct from the references cited by the Examiner, and that these claims are in full compliance with the requirements of 35 U.S.C. §112. The amendment and addition of the claims and the remarks herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112; but rather the amendments, additions and remarks are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

II. RESPONSE TO RESTRICTION REQUIREMENT

The June 18, 2001 Office Action required an election under 35 U.S.C. § 121 from among:

Group I. Claims 1-2, 5, 6, and 20-23, drawn to DNA, associated primers and vector and a method of making CaEss1, classified in class 536, subclass 23.5;

Group II. Claims 3-4, drawn to proteins, classified in class 530, subclass350;

Group III. Claim 7, drawn to a method for detecting *C. albicans* comprising a nucleic acid molecule, classified in class 435, subclass 6;

Group IV. Claim 8, drawn to a method for detecting *C. albicans* comprising detecting the presence of polypeptide, classified in class 435, subclass 7.1;

Group V. Claim 9, drawn to an antibody, classified in class 530, subclass 387.1;

Group VI. Claim 10, drawn to a diagnostic composition comprising the polypeptide, classified in class 424, subclass 184.1;

Group VII. Claims 11-13, drawn to a diagnostic composition comprising nucleic acid molecule class 536, subclass 23.1;

Group VIII. Claims 14-16 and 18, drawn to a compound and a method for preventing or treating *C. albicans*, classified in class 424, subclass 130.1; and

Group IX. Claims 17 and 19, drawn to an antiproliferative compound and a method for preventing human cell growth, classified in class 424, subclass 1.41

Pursuant to the telephone conversation of May 1, 2001 with Examiner Baskar, the election of Group I, with traverse, is affirmed. Group I includes claims 1, 2, 5, 6 and 20-23. It is respectfully asserted that claim 7 should be rejoined with Group I, as it is a method claim that is dependent on a Group I claim. To that end, please note that claim 7 has been cancelled by this amendment, but that new claims 32 and 33 replace it. Added claim 27 is based upon claim 5. Claims 28-31 correspond to cancelled claim 6; claims 34 and 35 correspond to cancelled claim 20; claims 36 and 37 correspond to cancelled claim 21; claim 38 corresponds to cancelled claim 22; and, claim 39 corresponds to cancelled claim 23. Therefore, Group I, now claims 1, 5, 6, and 24-39, is elected with traverse.

Reconsideration and withdrawal of the restriction requirement are respectfully requested in view of the remarks herewith.

The present claims represent a web of knowledge and continuity of effort that merits examination in a single application. For instance, the Group II amino acids and the Group I nucleic acids encoding them are drawn functionally to the same enzyme, CaEss1. With respect to these sequences, it is respectfully requested that the Examiner kindly note PCT Administrative Example 17, wherein a claim to DNA encoding protein X and another claim to protein X are deemed to have unity:

> Example 17
> Claim 1: Protein X
> Claim 2: DNA sequence encoding protein X.
> Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity between claims 1 and 2 is accepted.

In this case, the SEQ ID NO: 2 polypeptide is encoded by the gene of SEQ ID NO: 1.

Indeed the claims of Group I and II are related as the Group II amino acids and the Group I nucleic acids encoding them are drawn functionally to the same enzyme, CaEss1. The claims of Groups III and IV are related to one another, since both are drawn to a method for detecting *C. albicans*. The claims of Groups I, II, III and IV are related, as those of Groups III and IV are methods which detect the products of the Groups I and II claims.

Also, the claims of Groups VI and VII are both drawn to a composition for diagnosing *C. albicans,* and are thus related. Indeed, all the claims are directed to the *CaESS1* gene, portions thereof, expression products therefrom, and methods for using the gene and expression products.

In this regard, the Examiner's attention is respectfully requested to review MPEP § 808.02 which states, ". . . even with patently distinct inventions, restriction is not (emphasis added) required unless one of the following reasons appears:

1. Separate classification;
2. Separate status in the art; or
3. Different field of search . . ."

The claims of the present invention relate to compositions and methods for diagnosing, detecting, preventing and/or treating *Candida albicans* or associated symptoms, and to the process and products for preparing such compositions and methods.

Contrary to the guideline mandated by the MPEP, Groups II and V; Groups III and IV; and Groups VI, VIII and IX are, respectively, in the same classes. Further, Groups III and IV involve the same status in the art. Importantly, the claims in all nine Groups involve the *CaESS1* gene, its products and uses, thereby encompassing the same field of search. Thus, restriction is not appropriate.

Additionally, the Examiner's attention is further respectfully invited to review the text of MPEP § 803 which in part states:

> If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions (emphasis added).

It is respectfully asserted that Groups I-IX can be searched and examined in this application, as there is no undue or serious burden in searching and examining these claims together.

Thus, the restriction requirement is improper; and, it is respectfully requested that it be reconsidered and withdrawn, or at the very least, reformulated to encompass the claims pending via this Amendment.

III. THE REJECTIONS UNDER §112, FIRST PARAGRAPH, ARE OVERCOME

Claims 1 and 2 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. The Office Action contends that the specification allegedly does not contain a written description of the invention for a nucleotide sequence which has at least 70% homology to the nucleotide sequence of SEQ ID NO: 1. This rejection is respectfully traversed.

The cancellation of claim 2, along with the changes to claim 1, have rendered this rejection moot. Specifically, claim 1 now specifies the nucleic acid sequence being claimed, and new claims 24-26 provide further clarification. Thus, the rejection is obviated.

Claims 1, 2, 5 and 20-23 were rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly does not fully enable one skilled in the art to make and/or use the invention. The Office Action contends that the specification allegedly does not provide enablement for a nucleic acid molecule comprising a nucleotide sequence encoding any and all variants of CaEss1, any primer or probe which specifically binds to a nucleic acid molecule comprising a nucleotide sequence encoding any and all variants of CaEss1, and a method for obtaining any and all variants of isolated nucleic acid molecule encoding CaEss1 comprising performing a polymerase chain reaction on a sample to contain variants of CaEss1 using any primer or probe which specifically hybridizes thereto. This rejection is respectfully traversed.

The cancellation of claims 2 and 20-23, the addition of claims 24-39, and the changes to claims 1 and 5, have rendered this rejection moot. Claims 1 and 24-26 clarify the nucleic acid sequence being claimed. Further, dependent claims 27-31 specify the primer or probe which binds specifically to the nucleic acid of claim 1, claim 27 having been amended to reflect high stringency binding.

Even further still, claims 25 and 26 provide for 97% homology, with an algorithm for calculating homology, and recite that the nucleic acid molecule encodes a polypeptide having the enzymatic activity of CaEss1. Thus, claims 25 and 26 recite a percent homology, how it is

calculated, and a functional limitation. No undue experimentation is needed to practice claims 25 and 26. The skilled artisan can, from the disclosure in the application and the knowledge in the art, determine, without any undue experimentation, whether a nucleic acid molecule has at least 97% homology to SEQ ID NO: 1, and whether that molecule indeed encodes a product having the enzymatic activity of CaEss1.

Additionally, claims using the transitional phrases "consisting of" (claims 25, 28, 29, 33, 35 and 37) and "consisting essentially of" (claims 24, 26, 30 and 31) have been added. The Examiner is respectfully reminded of the case law defining the term "consisting essentially of", in which the phrase is defined as "occup[ying] a middle ground between closed claims that are written in a 'consisting of' format and fully open claims that are drafted in a 'comprising' format". *PPG Industries v. Guardian Industries,* 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). Furthermore, the term "consisting essentially of" is a permissible claim transition under the Guidelines and is used in the manner ascribed to it in the patent case law. It excludes elements that are found in the prior art or that affect a basic or novel characteristic of the invention. *See, e.g., In re Garnero,* 162 U.S.P.Q. 221 (C.C.P.A. 1969); *Ex parte Shepherd,* 185 U.S.P.Q. 480 (BOPA 1974); *Ex parte Hutchins,* 157 U.S.P.Q. 167 (BOPA 1967); *see also Zeigler v. Phillips Petroleum Co.,* 177 U.S.P.Q. 481 (5th Cir. 1973). Thus, this term also provides patentability to the claimed invention. Also, note that the "consisting essentially of" claims contain a functional recitation to provide a basic or novel characteristic of the invention and to assist in having the transition provide patentability.

In light of the amendment to the claims and the foregoing arguments, the pending claims are enabled by the specification and therefore, the rejection is obviated.

Consequently, it is respectfully requested that the Section 112 rejections be reconsidered and withdrawn.

IV. THE REJECTIONS UNDER §102 ARE OVERCOME

Claims 1 and 5 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,489,513 to Springer *et al.* This rejection is respectfully traversed.

Applicants' invention is directed to, *inter alia*, a gene essential for *Candida albicans* growth, the *CaESS1* gene, and diagnostic and therapeutic compositions and methods involving the gene, protein, or fragments thereof. Springer *et al.* do not teach or suggest either the

sequence of *CaESS1* or a primer or probe which specifically hybridizes to it. Rather, Springer *et al.* disclose a "gene probe", 431-19, which may or may not code for a functional gene product, and several 100 base pair oligonucleotide probes that hybridize with the gene probe. Furthermore, the probe of Spinger *et al.* has not been shown to encode CaEss1 or to specifically hybridize to SEQ ID NO: 1.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Springer *et al.* clearly does not contain all of the elements of the claimed invention, since neither the sequence of *CaESS1*, nor a primer or probe which specifically hybridizes to it, are disclosed. And note also the "consisting of" and "consisting essentially of" transitions and how these transitions, as well as functional recitations, distinguish over the art. Therefore, the cited document does not teach or suggest the present invention.

Claim 6 was rejected under 35 U.S.C. §102(b) as allegedly anticipated by Accession Numbers AA 182274 and Y 13120. This rejection is respectfully traversed.

Applying the Federal Circuit precedent outlined above, this rejection cannot stand. To wit, claims 5 and 27-31 call for probes, primers, or nucleic acid molecules that specifically hybridize to SEQ ID NO: 1, or specific sequences. Note the "consisting of" and "consisting essentially of" transitions and how these transitions, as well as functional recitations, distinguish over the art. Accession Numbers AA 182274 and Y 13120 do not contain all of the elements of the claimed invention. Further, accession numbers do not contain an enabling disclosure that would enable the skilled artisan to make and use the presently claimed invention.

Therefore, it is respectfully requested that the Section 102 rejections be reconsidered and withdrawn.

PATENT
454311-2200.1

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to any paper issuing other than a Notice of Allowance, another interview is respectfully requested and the Examiner is further respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for the interview.

CONCLUSION

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date.

Respectfully submitted,

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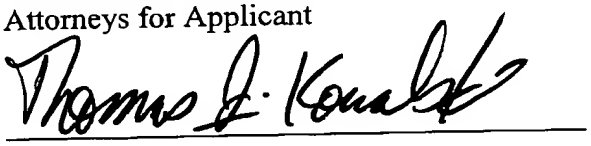

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THECLAIMS:

1. An isolated or purified nucleic acid molecule [comprising a]consisting of the nucleotide sequence [encoding CaEss 1, or having at least 70% homology thereto]set forth in Figure 1 (SEQ ID NO: 1).

5. A primer or probe which specifically hybridizes to the nucleic acid molecule of claim 1 [or 2].